

REMARKS

This Amendment is responsive to the PTO communication sent January 28, 2003 (referred to herein as the Office Action). Claims 1 and 3-79 are pending. By this Amendment, claims 1, 3-39, and 45-64 are cancelled as being non-elected inventions. Claims 40-44 and 65-79 are pending and under examination. Claims 40 and 79 have been amended without narrowing for the sake of clarity.

The title has been amended to better reflect at least some of the claims under consideration.

An abstract is enclosed; support for the abstract may be found at, e.g., page 1, lines 5-10, and page 45, lines 12-23. No new matter has been added.

A complete set of formal drawings is enclosed, showing Figures 1-16, on pages 1-14. Support for these drawings is found in the originally filed Figures 1-16, and no new matter has been added. No changes have been made to the drawings. Formal drawings 1-6 have already been submitted; formal drawings 7-16 are hereby submitted, and approval of these drawings is requested.

The Examiner is requested to provide Applicants with a copy of the completed PTO-1449 forms from the Information Disclosure Statements (IDS) that have been submitted for this application. Forms PTO-1440 have been submitted with an IDS on the following dates: December 17, 2001; January 29, 2002; May 10, 2002; June 21, 2002; October 4, 2002; and November 5, 2002.

The Examiner has indicated that claims 40 and 67 are duplicative since claim 40 recites "within 96 hours of the pancreatic islet cell transplant" and dependent claim 67 recites "after the pancreatic islet cell transplant". Office Action, item 5. It is respectfully submitted, however, that a person of ordinary skill would interpret "within 96 hours of the pancreatic cell transplant" as meaning before or after the pancreatic cell transplant after reading the specification, e.g.,

Figure 5. Figure 5 shows a tissue transplant, e.g., pancreatic cells, as occurring prior to the infusion of donor cells, e.g., a bone marrow transplant.

The Examiner has made a new matter rejection of claims 42-44, 65-73, and 75-79 under 35 U.S.C. 112, ¶ 1, on the grounds that the specification does not show that the applicants had possession of the claimed invention. Office Action, item 9. It is respectfully submitted that the claims are not new matter, as will be evident after reviewing the Application, including the portions of the Application as specifically pointed out herein: Claim 42 is supported at, e.g., page 44 line 22 to page 45 line 2, and Example 8, starting at page 41; Claim 43 is supported at, e.g., page 34, lines 6-15; Claim 44 is supported at, e.g., page 33 lines 15-22, page 45 lines 3-6; Claim 65 is supported at, e.g., page 43, lines 8-10; Claim 66 is supported at, e.g., page 15, line 19 to page 16 line 13, and page 43, lines 10-12; Claim 67 is supported at, e.g., page 43 lines 13-14, and Figure 5; Claim 68 is supported, e.g., at page 34 lines 6-9, and Figure 4; Claims 69 and 70 are supported at, e.g., page 31 line 1 to page 32 line 7; Claim 71 is supported at, e.g., page 33, lines 1-13; Claims 72 and 73 are supported at, e.g., page 32, lines 1-7; Claims 75-77 are supported at, e.g., page 4, lines 13-15; page 8, lines 1-4, and page 17, lines 4-9, page 30, lines 17-20, and page 32, lines 14-15; Claims 78 and 79 are supported at, e.g., page 18, line 12 and page 31, lines 9-12. In light of the support for the claims, the Examiner is requested to withdraw these rejections.

The Examiner has pointed out that the present claims are free of the prior art. Office Action, item 10.

The Examiner has rejected claims 40-44 and 65-79 under 35 U.S.C. 112, paragraph 2, as being indefinite for failing to particularly point out and distinctly claim the subject matter that is regarded as the invention. Office Action item 7, items 7A-7E. These rejections are addressed in detail, below.

With regards to claim 40, the Examiner has suggested that "administering a pancreatic cell transplant" be rewritten; accordingly, claim 40 has been rewritten to recite "transplanting a

"pancreatic cell" for the sake of clarity. Office Action item 7A. This change does not narrow the scope of the claim. The Examiner has also suggested that "infusing donor cells" be rewritten in terms of transplanting cells. Office Action item 7A. A review of the amended claim, however, suggests that this terminology would not necessarily be more clear. It is further noted that the specification makes reference to infusing cells at page 6, line 18 of the Application. The Examiner is therefore respectfully requested to withdraw the objection to the terminology of "infusing".

The Examiner has also argued that the metes and bounds of "mildly myeloablative" are unclear, indefinite, and undefined. Office Action item 7A. It is respectfully submitted, however, that the specification gives clear meaning to this term so that a person of ordinary skill in the art would understand it. The Application gives meaning to the term "mildly myeloablative" at, e.g., page 15, lines 16-17: "These methods are mildly myeloablative in the sense that they cause the death of only a small percentage of a patient's bone marrow cells. And a mildly myeloablative treatment avoids neutropenia, see Application page 30, lines 15-16. Further, the metes and bounds of "mildly myeloablative" are contrasted with, and distinct from, procedures that kill most or all of a patient's bone marrow cells, see Application page 15, line 14. A person of ordinary skill in the art is able to determine the quantity of a patient's bone marrow cells, and to measure neutropenia, see, e.g., Application page 37, lines 9-15. Moreover, breadth of a claim is not to be confused with indefiniteness. See In re Miller, 169 USPQ 597 (CCPA 1971). Since a person of ordinary skill is able to ascertain the scope of the claim, the Examiner is respectfully requested to withdraw this rejection.

With regards to claim 42, the Examiner has requested clarification of the term "donor chimerism". Office Action, item 7B. Donor chimerism is a term that refers to the amount of donor cells in a sample of cells taken from a recipient that has been transplanted with cells from the donor. As shown, for example, in Examples 7 and 8 of the Application, donor chimerism can

be measured after transplantation of cells from a donor to a recipient by analyzing a group of cells taken from the recipient to determine how many cells in the group have antigens that are specific to the donor 's body and not to the recipient's body. For example, the table in Example 8, at page 42 of the Application, entitled "Balb/c Donor Chimerism in PBL of C57BL/6 Mice at 8 Weeks Post-Transplant" shows the percentage of donor cells in chimeric mice created using the variables described in the table. The chimeric mice do not reject the donor cells, but continue to express them in amounts that may be measured by persons of ordinary skill.

With regards to claim 43, the Examiner has argued that the metes and bounds of "pretreatment" are unclear and that it is unclear which cells are pretreated. Office Action, item 7C and 7D. The administration of the cells is the cell pretreatment step, i.e., a step of pretreating a recipient with donor cells; the donor cells are not pretreated. Donor cell pretreatment is defined as a process of administering donor cells from a donor into a recipient; the donor cells are cells that display antigens to the recipient's immune system, see Application, e.g., page 34. lines 8-9. It is respectfully submitted that this definition would be clear to a person of ordinary skill in these arts; therefore the Examiner is requested to withdraw these rejections.

With regards to claim 79, the claim has been amended without narrowing its scope to provide sufficient antecedent basis, see Office Action, item 7E.

In view of the foregoing, it is submitted that this application is in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested.

The Examiner is invited to telephone the undersigned if the Examiner believes it would be useful to advance prosecution.

Respectfully submitted,



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